REMARKS

The present communication responds to the Office Action mailed March 23, 2004. In that Office Action, the Examiner rejected claims 1, 2, 6-9, 15-18, 20, 21 and 26.

Rejections under 35 U.S.C. § 102

Claim 1 of the present application recites a device for metered administration of a fluid drug to an injection area of a patient comprising a container having a piston for administering said fluid drug through an outlet of said container; a catheter connected to the outlet of said container, the catheter having a front end facing away from the outlet and being connected to an injection needle; a valve positioned between the outlet and the injection needle in a flow cross section of the fluid drug, the valve having an inlet end adjacent the outlet and an outlet end adjacent the injection needle, wherein the valve is designed to only permit flow of the fluid drug through the valve from the outlet to the injection needle if a fluid pressure in the direction of the needle exceeds a maximum possible pressure of a fluid column, which is a pressure at the bottom of the fluid column created by the fluid column when the container and catheter are filled and the container is suspended above the injection site to a height allowed by the catheter when extended; and a driven member driving the piston towards the catheter, wherein the piston is only held in the container by frictional forces of a side all at the container, such that advancing movement of the driven member and the piston is controlled to administer the fluid drug in a dosed manner through the outlet.

Claims 1, 2, 6-9, 15-18, and 26 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lee, U.S. Patent 3,759,425. The Examiner asserted that Lee discloses a device for metered administering fluid having each of the elements recited in claims 1, 2, 6-9, 15-18 and 26.

Lee discloses a piston valve syringe gun. More particularly, Lee discloses a syringe gun suitable for dispensing liquid. The syringe consists of a barrel (1), a piston-rod (2) having a combined piston head and inlet valve (3) and a thumb pad (5). The barrel (1) has a discharge valve (4) at its outlet end. Liquid is stored in a container outside of the piston valve syringe gun and injected through the piston-rod, through a central bore (15) of the combined piston and valve (3), through a flap (16) and into a barrel (1). From the barrel (1), the liquid forces a resilient

plate (9) to buckle, opening an inlet orifice (7). The liquid flows over the plate (9), down into a valve chamber, and out of the outlet orifice (8). The plate (9) does not retain its original shape and close the inlet orifice (7) until *all of the liquid has been dispensed.* As explained at Column 7, lines 45-62, dispensing of liquid is as follows:

> As the piston 2 is being withdrawn liquid within the piston-rod (fed from a container not shown in the drawings) flows through the central bore 15 of combines piston and valve 3, the withdrawal causing flap 16 to open, into the barrel 1 where it is retained ready to be dispensed. When it is desired to inject, pressure is applied to the thumb pad 5 and the liquid is forced against the portion of the resilient plate 9 closing inlet orifice 7, this portion of the plate buckles slightly and liquid flows over the plate, down into the valve chamber, and out of outlet orifice 8. It will be understood that pressure of the liquid will cause flap 16 to be pressed firmly over bore 15 thus preventing the liquid flowing back into the piston-rod. When all the liquid has been dispensed the plate 9 resumes its original shape and closes inlet orifice 7.

Claim 1 recites:

> a valve positioned between the outlet and the injection needle in a flow cross section of the fluid drug, the valve having an inlet end adjacent the outlet and an outlet end adjacent the injection needle, wherein the valve is designed to only permit flow of the fluid drug through the valve from the outlet to the injection needle if a fluid pressure in the direction of the needle exceeds a maximum possible pressure of a fluid column, which is a pressure at the bottom of the fluid column created by the fluid column when the container and catheter are filled and the container is suspended above the injection site to a height allowed by the catheter when extended;

The piston valve syringe gun of Lee does not include a fluid column nor a fluid column pressure created by the fluid column when the container and catheter are filled and the container is suspended above the injection site. As explained above, the only liquid contained within the piston valve syringe gun of Lee is the liquid fed from a container through the central bore (15) of the combined piston and valve (3) when the piston (2) is withdrawn. Nor does Lee disclose a

valve designed to only permit flow of the fluid drug through the valve from the outlet to the injection needle if a fluid pressure in the direction of the needle exceeds a maximum possible pressure of a fluid column. The plate (9) of Lee that seals the inlet orifice (7) does not retain its original shape and seal the inlet orifice (7) until all of the liquid has been dispensed. Lee does not teach or suggest any manner to cause the plate (9) to retain its shape and seal the inlet orifice (7) while under the pressure of a fluid column. Thus, it is respectfully submitted that Claim 1, and associated dependent claims 2, 6-9 and 15-16 are patentable over Lee.

Claim 17, as amended, recites "an ampoule containing the fluid drug having a piston for administering the fluid drug through an outlet of the ampoule." As described above, Lee discloses a piston valve syringe gun wherein liquid is stored in a container outside of the piston valve syringe gun and injected through the piston-rod, through a central bore (15) of the combined piston and valve (3), through a flap (16) and into a barrel (1). Lee does not teach or suggest an ampoule containing the fluid drug, the ampoule being a component of a device for the metered administration of a fluid drug. Thus, it is respectfully submitted that Claim 17, and associated dependent claims 18 and 20-21 are patentable over Lee.

Claim 26 recites "a container having an outlet, the container received in the housing and containing the fluid medication to be dispensed through the outlet" as well as "a valve connected to the outlet, wherein the valve is adapted to permit flow of the medication if a force exerted on the valve in the direction of the injection area exceeds a minimum valve opening force, which is equal to or greater than a maximum force that would be exerted on the valve by a fluid column having a height equal to the fluid flow pathway when extended vertically above the injection area." As described above in reference to Claims 17 and 1, Lee discloses neither a container containing the fluid medication to be dispensed nor a fluid column nor any manner to cause the plate (9) to retain its shape and seal the inlet orifice (7) while under the pressure of such a fluid column. Thus, it is respectfully submitted that Claim 26 is patentable over Lee.

Accordingly, it is respectfully requested that the rejection of Claims 1, 2, 6-9, 15-18, 20-21, and 26 as anticipated by Lee be withdrawn.

Claims 1, 2, 6-9, 15, 16, 17 and 26 were rejected under 35 U.S.C. 102(b) as being anticipated by Caldwell et al., U.S. Patent 4,935,009. The Examiner asserted that Caldwell discloses a device for metered administering fluid having each of the elements recited in claims 1, 2, 6-9, 15, 16, 17 and 26. Specifically, the Examiner referred to Figures 2, 2B and 4-6.

Applicants note that Figures 2A and 2B illustrate a cross section elevation of the pump means, syringe recoil mechanism, valve apparatus, and injection port of Figure 1. Figures 4 and 5 illustrate the device in particular valve positions. Figure 6 illustrates the device as it would be attached to a fluid reservoir, a maintenance intravenous fluid and to a patient. Accordingly, the present invention is limited to discussion of Figures 1 and 6.

Caldwell discloses a device designed for the rapid administration and vascular circulatory distribution of emergency intravenous drugs. As shown in Figure 6, when in use, a reservoir spike 5 of the device is connected to a parenteral fluid reservoir container 10. Upstream flexible tubing 20 leads from the reservoir container 10 to a valve apparatus 15. The valve apparatus 15 is connected to a pump means 30. The valve apparatus 15 connects to downstream flexible tubing 60 leading to a catheter or needle 70. A therapeutic parenteral fluid 76 may be attached to tubing 77 and a hypodermic needle 78. The needle 78 inserts into Y-site 62 leading to the tubing 60.

With reference to Figure 1 of Caldwell, during operation, the device is primed with reservoir fluid by compressing the plunger fully and releasing it several times in succession to entirely fill all tubings, connectors, the valve apparatus and syringe chamber with reservoir fluid. Fluid from the reservoir container 10 flow through the upstream tubing 20 to the inlet check valve 25. The fluid flows through the inlet check valve 25 to a valve-to-syringe connector 12. The fluid flows through the valve-to-syringe connector 12, through an outlet check valve 50 and into downstream tubing 60. The fluid flows through the downstream tubing 60 to a catheter or needle 70 for injection into the patient. Each of valves 25 and 50 permit one-way free fluid flow. In the case of the inlet valve 25, free fluid flow is permitted from the valve supply port 11 into the valve-to-syringe connector 12 or outlet check valve 50 while preventing fluid flow in the opposite direction. (Column 6, lines 19-24). In the case of the outlet valve 50, free fluid flow is

permitted from the valve apparatus body 16 into the injection port 55 while preventing fluid flow in the opposite direction. (Column 6, lines 38-42).

Thus, Caldwell teaches free flowing of fluid through the device and, ultimately, into the patient once the device is primed with reservoir fluid by compressing the plunger. Each of Claims 1, 17 and 26 recite a valve designed to only permit flow of a fluid through the valve from the outlet to the injection needle if a fluid pressure exceeds a specified pressure. Specifically, Claim 1 recites "a valve ... designed to only permit flow of the fluid drug through the valve from the outlet to the injection needle if a fluid pressure in the direction of the needle exceeds a maximum possible pressure of a fluid column," Claim 17 recites "a valve ... wherein the valve permits flow of the fluid drug through the valve from the inlet end to the outlet end when a fluid pressure exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug," and Claim 26 recites "a valve ... wherein the valve is adapted to permit flow of the medication if a force exerted on the valve in the direction of the injection area exceeds a minimum valve opening force ..." Caldwell does not teach a valve that only permits fluid flow after a certain pressure has been exceeded; Caldwell teaches free flow of the fluid through the valves 25 and 50.

Further, Caldwell teaches storing the fluid in a reservoir container. The fluid is not dispensed into the device until the device is primed by compressing the plunger. In contrast, each of claims 1, 17 and 26 recite a container or ampoule of the device containing a fluid. Specifically, Claim 1 recites "a container having a piston for administering said fluid drug through an outlet of said container, the container containing the fluid drug to be dispensed through the outlet," Claim 17 recites "an ampoule containing the fluid drug having a piston for administering the fluid drug through an outlet of the ampoule," and Claim 26 recites, "a container having an outlet, the container received in the housing and containing the fluid medication to be dispensed through the outlet ..." Caldwell does not teach a container or ampoule of the device containing a fluid; Caldwell teaches storing the fluid in a reservoir container that is connected to the device.

Thus, it is respectfully submitted that Claims 1, 17, and 26, and associated dependent claims 2, 6-9, 15, 16 and 20 are patentable over Caldwell. Accordingly, it is respectfully

requested that the rejection of Claims 1, 2, 6-9, 15, 16, 17 and 26 as anticipated by Caldwell be withdrawn.

Claims 1, 2, 6-9, 15, 16 17, 18, 20, 26 were rejected under 35 U.S.C. § 102(b) as being anticipated by Winnard, U.S. Patent 3,601,151. The Examiner asserted that Winnard discloses a device for metered administering fluid having each of the elements recited in claims 1, 2, 6-9, 15-18 and 26. Winnard discloses a nonreturn valve for medical uses – or a one-way valve.

The valve of Winnard includes a plastic body formed of a spigot section 11 and a socket section 10. A bore defining a fluid path through the device is coaxial with the sections 10 and 11 making up the body. A valve closure member 17 of rubber or rubberlike material is located over a stem 15 of the spigot section 11 in the manner of a sock. The leading end 19 of the socket section 10 is coupled into a catheter 20 while the trailing end 21 of the spigot part 11 is equipped with a connecting cup or compartment into which a conventional syringe 22 may be fitted. By pumping air into the valve, the sock 17 bellows outwardly under pressure so that the air may pass through the valve between the stem 17 and adjacent sidewalls 23 of the sock 17. To deflate the balloon, a needle 26 may be passed through the base 25 of the sock 17, the needle carrying a bore through which the air escapes.

Thus, Winnard teaches a valve which yields under pressure applied through the stem bore to permit fluid to pass from the stem through the body bore. Winnard does not teach or suggest a valve designed to only permit flow of a fluid through the valve from the outlet to the injection needle if a fluid pressure exceeds a specified pressure. Claim 1 recites "a valve ... designed to only permit flow of the fluid drug through the valve from the outlet to the injection needle if a fluid pressure in the direction of the needle exceeds a maximum possible pressure of a fluid column," Claim 17 recites "a valve ... wherein the valve permits flow of the fluid drug through the valve from the inlet end to the outlet end when a fluid pressure exerted on the inlet end of the valve exceeds a pressure on the inlet end caused by the dead weight of the fluid drug," and Claim 26 recites "a valve ... wherein the valve is adapted to permit flow of the medication if a force exerted on the valve in the direction of the injection area exceeds a minimum valve opening force ..."

Further, Winnard does not teach or suggest a container or ampoule of a device containing a fluid. Claim 1 recites "a container having a piston for administering said fluid drug through an outlet of said container, the container containing the fluid drug to be dispensed through the outlet," Claim 17 recites "an ampoule containing the fluid drug having a piston for administering the fluid drug through an outlet of the ampoule," and Claim 26 recites, "a container having an outlet, the container received in the housing and containing the fluid medication to be dispensed through the outlet ..." In contrast, Winnard teaches that the valve may be used for removing samples of blood from the human body. (Column 2, lines 41-43). In such a situation, the human body contains the fluid.

Thus, it is respectfully submitted that Claims 1, 17, and 26, and associated dependent claims 2, 6-9, 15, 16, 18 and 20 are patentable over Winnard. Accordingly, it is respectfully requested that the rejection of Claims 1, 2, 6-9, 15, 16 17, 18, 20 and 26 as anticipated by Winnard be withdrawn.

Claims 1, 2, 6-9, 15 and 26 were rejected under 35 U.S.C. § 102(b) as being anticipated by Cardenas, U.S. Patent 5,616,133. The Examiner asserted that Cardenas discloses a device for metered administering fluid having each of the elements recited in claims 1, 2, 6-9, 15-18 and 26.

As discussed in the response filed December 17, 2003, Cardenas discloses a syringe for an epidural catheter. More particularly, Cardenas discloses a special epidural catheter syringe, an epidural catheter connector, and a continuous epidural tubing connector to provide mechanical lockouts to prevent epidural anesthetic from being injected intravenously and to prevent medications intended for intravenous use from being injected into the epidural catheter. In column 3, lines 18-21, Cardenas discloses that when the plunger (14) is pulled out of the syringe (10) to draw in liquid, the movable valve member (34) moves to the right until the legs (4) of the valve member (34) abut the first end wall (47) of the valve chamber (36). This is *contrary to the claimed invention* in that claim 1 recites that the valve is designed to only permit flow of the fluid drug through the valve from the outlet to the injection needle if a fluid pressure in the direction of the needle exceeds a maximum possible pressure of a fluid column when the container and catheter are filled and the container is suspended above the injection site to a height allowed by the catheter when extended. Further, to prevent human errors which are

described in the background of Cardenas, Cardenas provides a special epidural catheter syringe which an only inject into a special epidural catheter connector. In column 4, lines 46-51, Cardenas describes that "the syringe (1) cannot be used to inject directly into a patient's vein or intravenous line. In fact, the only way liquid can leave the special epidural catheter syringe 10 is by connecting the syringe 10 to a special epidural catheter connect 32, as shown in FIGS. 3 and 4." Accordingly, Cardenas does not disclose or suggest, and in fact *teaches away from*, having a catheter connected to the outlet of a container which includes a piston, and the catheter having a front end being connected to an injection needle as recited in claim 1.

In the Office Action, the Examiner responded to these argument by stated that the Cardenas reference teaches the claimed structure and would be capable of performing the possible function of the claimed structure. The Examiner stated that since this is an apparatus claim, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. This statement by the Examiner ignores the fact that Cardenas *does not* teach the claimed structure and, in fact, *teaches* away from the claimed structure. Consequently, the Cardenas device *would not* be capable of performing the possible function of the claimed invention.

As stated above, in column 3, lines 18-21, Cardenas discloses that when the plunger (14) is pulled out of the syringe (10) to draw in liquid, the movable valve member (34) moves to the right until the legs (4) of the valve member (34) abut the first end wall (47) of the valve chamber (36). This is *contrary to the claimed invention* in that claim 1 recites that the valve is designed to only permit flow of the fluid drug through the valve from the outlet to the injection needle if a fluid pressure in the direction of the needle exceeds a maximum possible pressure of a fluid column when the container and catheter are filled and the container is suspended above the injection site to a height allowed by the catheter when extended. Cardenas *does not* teach or suggest a valve designed to only permit flow of the fluid drug through the valve from the outlet to the injection needle if a fluid pressure in the direction of the needle exceeds a maximum possible pressure.

Further, as stated above, in column 4, lines 46-51, Cardenas describes that "the syringe (1) cannot be used to inject directly into a patient's vein or intravenous line. In fact, the only way liquid can leave the special epidural catheter syringe 10 is by connecting the syringe 10 to a special epidural catheter connect 32, as shown in FIGS. 3 and 4." Accordingly, Cardenas *does not* teach or suggest having a catheter connected to the outlet of a container which includes a piston, and the catheter having a front end being connected to an injection needle as recited in claim 1.

Accordingly, Cardenas *does not* disclose each of the claimed features. Claims 1, 17, and 26 each claim the essence of the above discussed features. Applicant therefore respectfully submits that claims 1, 17, 26 and dependent claims 2, 6-9, and 15 are patentable over Cardenas.

New claims

New claims 37 and 38 have been added. These new claims are supported by the originally filed claims, and support is also found at at least pages 5, line 13 – page 6, line 6 and page 8, lines 6-12.

Claim 37 is directed to an administering device such as is used, for example, in diabetes treatment as a portable infusion pump for self-administering insulin. Such infusion pumps typically comprise the medicine container and the conveying means compactly in a single casing. It follows from claim 37 that, as is common in such infusion pumps, in order to exchange the medicine container a connector casing comprising a connecting needle is connected to its outlet, wherein once the medicine container has been exchanged, the connecting needle is pierced through the membrane sealing the new container at its outlet in order to establish the connection to the infusion catheter. The membrane is pierced automatically when the connector casing is connected to the container outlet.

Since, as set forth in new claim 37, the connector casing of the connecting needle also simultaneously mounts the safety valve, and if the fluid-guiding components are exchanged together with the container when the container is exchanged, as is advisable for reasons of hygiene, then said fluid-guiding components can likewise be exchanged in a single and, by its nature, unavoidable disconnecting process and equally unavoidable connecting process. This

simple disconnecting and connecting, which requires no hand operations in addition to the disconnecting and subsequent connecting which is necessary, is advantageous in self-administering medicines, i.e., in cases in which older people or youths, well or less well trained people or people with, for example, amblyopia exchange said components in everyday situations. In these cases, it is particularly advantageous that additional hand operations do not also have to be learned or performed in order to exchange the valve, but rather that the valve is automatically exchanged so to speak by the usual hand operations for detaching and connecting the catheter.

Claim 38 depends from claim 37 and is allowable for the same reasons, and further in view of its additional recitations.

Conclusion

The above amendments should not generate any additional claim fees. However, a petition to extend the time to respond (from June 23, 2004 until September 23, 2004) is being submitted herewith, along with a check to cover the fee associated with the petition. The Office is also hereby authorized to charge any fee deficiency associated with this communication or the petition to Deposit Acct. 04-1420.

This application is in allowable form, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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